

What happens to Yellow Card reports and how is the information used?

The Medicines and Healthcare products Regulatory Agency (MHRA) acknowledges each Yellow Card report we receive. We may also ask you for additional details if this will help during assessment of the report.

- ◆ All reports are entered onto our database, which our staff analyse to look at the relationship between medicines and side effects.
- ◆ We consider whether the risk is common or serious, and decide whether we need to take any action.
- ◆ We may add warnings to the product information or patient information leaflet that comes with the medicine.
- ◆ We may update information on how the medicine should be used - for instance, limiting the dose, or advising that it should not be used by particular groups of patients.
- ◆ Information may be published in our monthly Drug Safety Update bulletin. Register to receive it at www.mhra.gov.uk/drugsafetyupdate
- ◆ Rarely, we may take the medicine off the market, but only if we consider that the risks of the medicine outweigh its benefits.

Any information provided to us is kept safe, secure and confidential. No details that could identify you or your patient(s) will be passed on without your permission.

Where can I get more information, Yellow Cards or additional materials?

- ◆ Additional information, including printable forms, can be found at www.mhra.gov.uk/yellowcard
- ◆ Alternatively, call the Yellow Card Information Service freephone on 0800 731 6789.

You can find out more about the suspected Adverse Drug Reactions which we have received at www.mhra.gov.uk/daps.

If you are in an area covered by one of our regional Yellow Card Centres, you can also contact them for more information:

Mersey

www.liv.ac.uk/~druginfo/csm

0151 794 8206

Northern & Yorkshire

www.nyrdtc.nhs.uk

0191 260 6181

Scotland

www.yccscotland.scot.nhs.uk

0131 242 2919

Wales

www.yellowcardwales.org

029 2074 4181

West Midlands

www.yccwm.org.uk

0121 507 5672

YellowCard

Helping to make medicines safer

The Yellow Card Scheme — Reporting Adverse Drug Reactions

Key facts

- ◆ Health professionals are vital reporters to the Yellow Card Scheme - the UK's voluntary scheme for reporting adverse drug reactions. This leaflet tells you more about the Yellow Card Scheme with guidelines on how to report.
- ◆ The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines - your report will help us safeguard public health.
- ◆ You only need to **suspect** that an adverse drug reaction was caused by a medicine to report it.
- ◆ If you are sure an adverse drug reaction has been reported by someone else, only report it to us if you can add additional information.
- ◆ Please don't assume someone else will report an adverse drug reaction you witness.

Help make medicines safer for everyone

www.mhra.gov.uk/yellowcard

MHRA

What should I report to the Yellow Card Scheme?

Healthcare professionals can help improve medicines safety by reporting suspected Adverse Drug Reactions via the Yellow Card Scheme. Although patients and the wider public can also report, healthcare professionals send the vast majority of Yellow Cards. Please continue to use the Yellow Card Scheme to tell us about:

- ◆ **All** suspected adverse drug reactions for **new medicines** - identified by the black triangle ▼ symbol.
- ◆ **All** suspected adverse drug reactions occurring in **children**, even if a medicine has been used off-label.
- ◆ **All serious*** suspected adverse drug reactions for established vaccines and medicines, including unlicensed medicines, herbal remedies, and medicines used off-label.

*Reactions which are fatal, life-threatening, disabling or incapacitating, result in or prolong hospitalisation, or medically significant are considered serious.

If you are unsure, please report anyway

Must I be sure that a reaction was caused by the medicine before reporting it?

No. We know that it can be hard to tell whether a medicine caused a possible side effect. You only need to suspect that the reaction was related to the medicine to send a Yellow Card.

How do I report a suspected adverse drug reaction?

- ◆ the easiest way to report is **online** at www.mhra.gov.uk/yellowcard
- ◆ **complete a paper Yellow Card form** which you can post to FREEPOST YELLOW CARD. Yellow Cards can be found in the BNF, MIMS, ABPI compendium or obtained by calling the Yellow Card Information Service freephone on **0800 731 6789**.

What if I think someone else has or will be reporting the adverse drug reaction?

If you are sure someone else has reported or will do so, please only report yourself if you think you can provide additional information. However, if you are unsure, please always report anyway. Our systems identify duplicate reports so the same case is not counted twice. Never assume someone else will report an adverse drug reaction that you witness.

Can patients report suspected Adverse Drug Reactions?

Yes they can. Again, it is simplest for them to report online at www.mhra.gov.uk/yellowcard so that we can receive and process reports as quickly as possible. Patient Yellow Card forms are also available from GP surgeries and pharmacies. Patients can also report by calling the Yellow Card freephone line on **0808 100 3352**.

What information should be included in a Yellow Card report?

Four essential pieces of information need to be included:

1. The side effect(s).
2. Information about the person who experienced the side effect (as a minimum we need their initials, sex, or age at the time of the side effect).
3. The name of the medicine(s) thought to have caused the side effect(s).
4. Your name and full address, so that we can acknowledge your report and contact you for further information if necessary.

In addition to this essential information, please complete as much of the Yellow Card as you can before sending it to us.

What difference does my Yellow Card report make?

Yellow Cards are an important source of information on side effects. Warnings were added to the product information for the smoking-cessation drug varenicline after we received Yellow Cards reporting suicidal ideation. Yellow Cards of adverse drug reactions to the former obesity drug rimonabant contributed to this drug being withdrawn - new evidence meant the risks were considered to outweigh any benefits.